## REMARKS/ARGUMENTS

Claims 1, 5-9, 19, 20 and 32-38 are active. This Amendment replaces the Amendment filed November 4, 2003, reiterates the previously proposed amendments, but corrects some typographical errors in the non-amended claim language. Specifically, in Claim 1, line 3, the term "non-liquid" has been replaced with the proper term "solid" and in line 4 the word "control" with the proper term "controlling". Similarly, changes have been made in lines 5 and 7 of Claim 36.

## SUPPORT FOR THE AMENDMENT

Independent Claims 1 and 32 have been amended to indicate that the medicine storage layer consists of the medicine(s) or the medicine(s) and a vehicle. Support for this amendment is found in the specification, Examples 1, 2, 4 and 5, where the medicine storage layer consists of a medicine and in Examples 3 and 6, where it consists of a medicine and a vehicle. Page 5, lines 2-12, of the specification also describes vehicles. Accordingly, the Applicants do not believe that any new matter has been added.

## Rejection—35 U.S.C. §103(a)

Claims 1, 4-9, 19, 20 and 32-38 were rejected under 35 U.S.C. 103(a) as being unpatentable over Pfister et al., U.S. Patent No. 5,232,702, in view of Mantelle, U.S. Patent No. 5,446,070 and further in view of Wick et al., U.S. Patent No. 5,662,926. The Applicants submit that the cited prior art does not disclose or suggest the invention for the following reasons.

The Applicants reiterate their prior arguments with respect to Pfister et al., which does not disclose or suggest a solid medicine storage layer in combination with a permeation controlling film. As noted in the rejection, Pfister is directed to a device with a liquid

reservoir. Such a liquid reservoir is quite distinct from the solid medicine storage layer of the invention. Accordingly, even were one with ordinary skill in the art motivated to incorporate the medicines of Mantelle into the liquid reservoir of Pfister and with the adhesives of Wick et al., this would not result in the present invention having a solid reservoir with a permeation controlling film which when activated by moisture, allows a medicine to permeate, dissolve, disperse or diffuse through the permeation controlling film into the skin. This solid reservoir, as shown in the Examples in the specification and in the attached Declaration, is an important feature of the invention that allows a medicine to be stored in a more stable form by restraining its degradation or decomposition.

The Examiner agrees on page 5 of the Official Action that Pfister does not teach a medicine storage layer comprising one or more medicines that permeate, dissolve, disperse, or diffuse into a plasticized permeation controlling film which has been activated by moisture. However, page 6 of the Official Action expresses concern that the liquid reservoir of Pfister is "similar in means and effect of the medicine storage layer and serves and identical purposes as that of the medicine storage layer".

To dispel this concern, the Applicants point out that the present invention provides a percutaneous absorption preparation, which, even when a medicine is an unstable compound in a polymer such as an adhesive and poly(vinyl alcohol), serves to stabilize the medicine by restraining is decomposition and deterioration during preservation, and which subsequently allows the medicine to move to the layer of adhesive and to the skin for absorption at the time of application, see the specification, page 2, lines 5-13 and Test Examples 1 and 2.

Incorporation of a medicine into an adhesive or into a medicine storage layer comprising a polymer such as poly(vinyl alcohol) can reduce its stability and result in degradation of the medicine over time. Comparative Examples 1-3 shown that incorporation of the medicine into an adhesive resulted in degradation of the medicine over time compared

to Examples 1-6 where a solid medicine storage layer was used, see Table 2 on page 13 and compare Examples 4 and 5 with Comparative Examples 2 and 3; and compare Examples 1-3 and 6 with Comparative Example 1. Moreover, as shown in the attached Declaration of Mr. Kaname Nakahara, when the medicine nicorandil is contained in a polymer, such as poly(vinyl alcohol), the stability of the medicine lowers. As shown by the above data, the constitution of the medicine storage layer exerts a significant influence on the stability of a medicine. Accordingly, in view of the lack of disclosure or suggestion in the cited prior art for producing a solid medicine storage layer in combination with a permeation controlling film, and in view of the demonstrated superior medicine stability in products containing a solid medicine storage layer, the Applicants respectfully submit that this rejection may now be withdrawn.

## CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

Norman F. Oblon
Attorney of Record
Registration No. 24,618

Thomas M. Cunningham
Registration No. 45,394

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 08/03)
TMC/bu